

**OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee (DTAC)
Report to the Board of Directors
November 12-13, 2014
St. Louis, Missouri**

**Daniel Kaul, MD, Chair
Cameron Wolfe, MD, Vice Chair**

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This report reflects the work of the OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee from June through September, 2014.

Action Items

1. Aligning OPTN/UNOS Policy with the 2013 PHS Guideline for Reducing Transmission of HIV, HBV, and HCV through Solid Organ Transplantation

[Public Comment: March 14 – June 12, 2014](#)

The Final Rule §121.4 (OPTN policies: Secretarial review and appeals.) notes that the OPTN Board of Directors is responsible for developing policies that are consistent with recommendations of the Centers for Disease Control and Prevention (CDC) to test potential organ donors and following transplant recipients to prevent the spread of infectious disease. The June 19, 2013, release of the [PHS Guideline for Reducing Human Immunodeficiency Virus \(HIV\), Hepatitis B Virus \(HBV\), and Hepatitis C Virus \(HCV\) Through Organ Transplantation](#) led to a systematic review of related OPTN policies.

During its September 22, 2014 teleconference, the Committee reviewed final proposed policy language (**Exhibit A**) alongside policy changes implemented on September 1, 2014. This final language included:

- minor modifications based upon public comment feedback received
- stylistic edits suggested by UNOS staff for clarity, and
- a small portion of language from the Living Donor Committee's proposed changes to transmissible disease testing in Table 14-2, as both committees had a number of proposed modifications to this particular section of policy

After a line-by-line review of each of the proposed modifications, the Committee voted unanimously to recommend the proposal for consideration by the Board of Directors (12 support, 0 oppose, 0 abstentions)

RESOLVED, that additions and modifications to Policies 2.2 (OPO Responsibilities), 2.4 (Deceased Donor Medical and Behavioral History), 2.7.B (Informing Personnel), Table 14-2 (Requirements for Living Kidney Donor Medical Evaluations) with the exception of NAT-related requirements, 15.3 (Informed Consent of Transmissible Disease Risk), 15.3.A (Deceased Donors with Additional Risk Identified Pre-transplant), 15.3.B (Deceased Donor at Increased Risk for Transmission of Blood-borne Pathogens), and 16.7.B (Vessel Storage) as set forth in Exhibit A, are hereby approved, effective February 1, 2015.

FURTHER RESOLVED, that additions and modifications related to donor nucleic acid testing (NAT) requirements in Policy 2.9 (Required Deceased Donor Infectious Disease Testing) and Table 14-2 (Requirements for Living Kidney Donor Medical

Evaluations) as set forth in Exhibit A, are hereby approved, effective pending programming and notice to the OPTN membership.

2. Living Donor Screening Guidance for Seasonal and Geographically Endemic Infectious Diseases

Public Comment: n/a

Current living donor screening requirements for West Nile Virus, Strongyloides, and Chagas have proved challenging for living donor recovery hospitals. Assistance was requested in developing a protocol for this required screening. Specifically, living donor recovery hospitals have asked for assistance in defining “endemic areas” as referenced in Policy Table 14-2: Requirements for Living Kidney Donor Medical Evaluations (Endemic Transmissible Diseases).

A Subcommittee was formed to determine a path forward with this effort, reviewing the Committee’s aggregate data on donor-derived disease transmissions for frequently reported infections of these types. After reviewing this information, the Subcommittee developed a document that would be helpful to the transplant community at both the transplant coordinator and physician level, and incorporated a table of frequently seen infections as well as text to provide further detail on each regarding risk factors, signs and symptoms of infection, and potential testing or imaging studies that may be helpful to the living donor recovery hospital evaluating potential donors (**Exhibit B**).

The Subcommittee’s draft guidance was reviewed by the full Committee during its September 9, 2014, teleconference. After careful consideration, the Committee voted to recommend the guidance document for consideration by the Board of Directors (12 support, 0 oppose, 0 abstentions):

RESOLVED, that the guidance document entitled “Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Living Donor Evaluation,” as set forth in Exhibit C, is hereby approved, effective November 13, 2014.

Committee Projects

3. Modifications to How New Donor Information Received Post-Transplant is Reported to Recipient Centers

Public Comment: January, 2015 (estimated)

Board Consideration: November, 2015 (estimated)

Committee and Department of Evaluation and Quality reviews have highlighted a number of instances where communication delays or failures for new donor information learned post-transplant led to potential transplant recipient morbidity or mortality. The Committee seeks to improve communication regarding new information that is critical to recipient care, enhance recipient safety, and help to prevent or quickly react to potential donor-derived disease transmission. As part of this effort, the Committee also looked closely at the current patient safety contact requirement, as it is not functioning as efficiently in some institutions as others, and has presented challenges in communicating important information in some cases.

This project utilized a failure mode and effects analysis (FMEA) approach. The use of FMEAs was an initiative identified in the 2012 OPTN Strategic Plan. Committee members received an update on this effort and the FMEA to analyze the process used to communicate this information and all of the potential failure points that could lead to potential recipient harm during its August 14, 2014, meeting. The FMEA Joint Subcommittee, including representatives from the OPO, Transplant Coordinators, and Transplant Administrators Committees, had met the day prior in Chicago to begin finalizing its work.

After reviewing the list of failure points and the final rankings assigned based upon discussions from the various conference calls, the Joint Subcommittee began to brainstorm on action plans to address each (**Exhibit D**). These actions might include, policy modification, education and sharing of best practices, and automation of process to reduce human error. The Joint Subcommittee voiced strong support for updates to the patient safety contact list within DonorNet® through the development of a platform similar to the OPO console, where transplant hospitals can note on call coordinators in real time. This, in conjunction with allowing the posting of post-transplant test results as attachments in DonorNetSM, were noted as high impact changes that would benefit both the OPO and transplant hospitals. Staff took these recommendations back to UNOS IT staff for consideration.

This careful analysis will provide evidence base for policy modification and possible automation of communication meant to enhance patient safety. Based on the scope of this effort, a two-step process is planned. The Committee is working to develop a public comment proposal for release in January 2015 to address concerns related to reporting requirements. This will be followed with potential modifications to automate many parts of the communication process that will reduce opportunity for human error; therefore, improving upon patient safety.

4. What to do when Infectious Disease Screening Results Affecting Match Runs are Updated

Public Comment: *January 2015 (estimated)*

Board Consideration: *June 2015 (estimated)*

There is currently no requirement in policy to re-generate a match run if there is a change in donor infectious disease screening results that would impact a candidate's appearance on a match run. Currently, four serology results are used to screen potential recipients on or off of an organ match run. They include:

- HBV
- HCV
- Human T-Lymphotropic Virus (HTLV) (if donor screening was completed)
- Cytomegalovirus (CMV) (pertinent only for the intestine match run, though several joint subcommittee members agreed that this is no longer clinically relevant)

After a lengthy hiatus necessitated by work on aligning Policies with the 2013 PHS Guideline, the Joint Subcommittee considering this effort was reconvened in July and September 2014 to revisit this issue. The group worked to develop draft policy language to address requirements for when a match run should be re-executed. A great deal of discussion focused upon instances when an organ is provisionally accepted for a recipient, but a positive result for one of the tests listed above would result in this intended recipient

not appearing on the re-executed match run due to screening preferences. For example, a liver candidate may accept an offer where HCV results are noted as pending. This candidate was recorded on the waiting list as not willing to accept an HCV positive organ, yet when the donor's positive results are received the candidate's care team and the patient are willing to accept the positive organ due to the severity of illness or risk of death without transplant at that time. Joint Subcommittee members raised concerns about withdrawing offers of this type, when some candidates may have traveled a great distance to the transplant hospital and recovery teams may already be en route or at the donor hospital. Additionally, a requirement to re-execute a match run in this instance, especially for liver candidates, might introduce new potential recipients who did not appear on the original match run or potential recipient whose MELD or PELD score had changed, causing the ranking of the match run to change, sometimes dramatically in a short period of time.

The Joint Subcommittee ultimately determined that, in these instances, the match run must be re-executed unless an organ has already been accepted for a potential transplant recipient when new positive infectious disease results (as listed above) are discovered that will impact appearance on the match run. They proposed that:

- The host OPO must:
 - Report this new infectious disease information to each transplant hospital that accepted an organ offer as soon as possible, but within an hour of receipt of the new test result.
 - Re-execute the match run if the intended recipient declines the offer after receiving this updated information. Allocation must then be completed using the updated match run.
- The intended recipient's transplant hospital must:
 - Inform the potential recipient of the donor's new positive infectious disease test result
 - Meet the requirements of *Policies 15.3.A: Deceased Donors with Additional Risk Identified Pre-Transplant* and *5.4.F Allocation to Candidates Not on the Match Run* for communication and documentation of this new information if the potential recipients proceeds with transplant after receipt of this new donor information.

Draft policy to incorporate these proposed ideas will be shared with the Joint Subcommittee for a final vote and then circulated to the committees represented in this group, with public comment sought in January 2015.

Committee Projects Pending Implementation

5. Review of Minimum Screening Requirements for Deceased Donor Evaluation

<i>Public Comment:</i>	<u>September 6 – December 6, 2013</u>
<i>Board Consideration:</i>	<i>June 2014</i>
<i>Projected Implementation:</i>	<i>Third quarter, 2015 (Estimated)</i>

The Board approved modifications to minimum screening requirements for deceased donor evaluation during its June 2014 meeting. Policy language was implemented prior to programming, but programming will enhance patient safety and reduce free-text data entry burden entry for OPOs and review for transplant hospitals.

6. Improvements to Potential Donor-Derived Disease Event Reporting in the Improving Patient Safety Portal

Public Comment: n/a
Board Approval: June 2013
Projected Implementation: Second quarter, 2015 (Estimated)

The Board approved enhancements to the portal used to report potential donor-derived disease transmission events (PDDTE) in June 2013. The current system for reporting PDDTE relies heavily on an open text field where the submitter provides a narrative. In an effort to standardize the information received through the system, staff recommended the addition of drop down fields for basic information received or requested during the reporting of every potential donor-derived disease transmission event. These enhancements will streamline the reporting process for the submitter and provide clear information up front for case processing and management by UNOS staff. The Executive Committee prioritized and scheduled the implementation of this project during its April 9, 2014 teleconference.

7. Reporting Whether Donor Screening Tests are Completed using Qualified Specimens

Public Comment: [March 19 – July 16, 2010](#)
Board Approval: [November 2010](#)
Projected Implementation: Fourth quarter, 2015 (Estimated)

The Board approved a proposal to modify requirements for screening potential donors, including reporting of whether individual deceased donor screening tests were completed using a (non-hemodiluted) qualified specimen. Policy was implemented without fields to collect this information in DonorNet®. The Executive Committee prioritized and scheduled the implementation of this project during its April 9, 2014 teleconference.

Implemented Committee Projects

None

Review of Public Comment Proposals

The Committee has not yet reviewed any of the proposals released for public comment on September 29, 2014.

Other Committee Work

8. Recorded Town Hall Meeting with CDC

The Committee continues to develop educational materials to help the transplant community better understand the application of the 2013 [PHS Guideline for Reducing Human Immunodeficiency Virus \(HIV\), Hepatitis B Virus \(HBV\), and Hepatitis C Virus \(HCV\) Through Organ Transplantation](#). In addition to the [frequently asked question \(FAQ\) sheet](#) posted to the OPTN website in February 2014, representatives from the Committee, including its ex officio CDC representative, and Operations & Safety Committees worked with Instructional Innovations staff to develop a script for a recorded town hall meeting. The result was a two-part series that walks through questions related to identifying increased risk organ donors and offering scenarios that have come up in questions to UNOS since implementation of the requirement to use the 2013 Guideline to make this determination. This recording will be posted to the OPTN website in mid-October. The Committee believes this partnership with the CDC will be beneficial to the transplant community, and plans a second town hall in 2015 to address the additional changes proposed to the board in item one of this report.

9. Case Review

The Committee continues its review of potential donor-derived disease transmission events reported to the OPTN in 2014. As of September 25, 2014, 192 reports have been submitted to the Committee for consideration. This trend indicates that the year-end total may surpass the 2013 total of 284 cases reviewed and classified by the Committee.

The Committee received an update on the total number of reports to the Improving Patient Safety portal, including duplicate reports, and brainstormed regarding ways to reduce the number of unnecessary reporting. The increase in case numbers is attributed to a number of OPOs proactively reporting all positive donor cultures, even those that would be addressed by standard post-transplant antibiotic prophylaxis. Committee leadership continues to consider education and policy modification to reduce potentially unnecessary reporting and committee member burden while continuing to enhance patient safety.

As part of this analysis, the Committee also reviewed updated data on variation among donor service areas in the number of cases reported to the Improving Patient Safety Portal (**Exhibit E**). Several Committee members shared practices from their own institutions or regions for determining what cases should be reported to the OPTN as potential donor-derived disease transmission events. This information may be helpful in modifications to policy addressing these requirements. The Committee will be taking a new project idea to the Policy Oversight Committee for consideration in January 2015 related to these concerns.

10. Review of Current Committee Abstracts and Manuscripts in Development

Part of the Committee's charge is to provide education and guidance to the transplant community toward preventing future disease transmission. Therefore, the Committee develops various papers and presentation to provide transplant professionals with new information, education and guidance to the transplant community toward preventing future disease transmission. The Committee heard updates from the authors of ongoing abstracts and manuscripts that are planned as tools to continue educating the transplant community regarding potential donor-derived disease transmission and enhancing patient safety. Additionally, Committee members who presented DTAC-related data at the 2014 World Transplant Congress shared brief overviews of their presentations with new committee members and any plans for continuing or expanding on these efforts.

Committee members also began brainstorming for abstract ideas that might be of interest to the various professional societies in 2015.

Meeting Summaries

The committee held meetings on the following dates:

- August 14, 2014
- September 9, 2014
- September 22, 2014
- Case review calls on the second Thursday of each month

Meetings summaries for this Committee are available on the OPTN website at: <http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=95>.